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54 Coated coloured intagliated articles.

57 Coated articles, for example coloured pharmaceutical tablets, bearing highlighted intagliations. The articles are coloured intagliated articles bearing at least one film coat comprising at least one optically anisotropic substance, for example magnesium carbonate, and at least one film coating agent. Process for manufacturing said articles.

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TITLE: COATED COLOURED INTAGLIATED ARTICLES

This invention relates to coated coloured intagliated articles on which the intagliations are highlighted.

In order that the invention may be the more easily comprehended, two expressions used in this specification will now be defined:

"intagliated article" - The word "intagliated" is related to the word "intaglio", which essentially means a figure or mark cut into any solid material. In one dictionary the word "intagliated" is defined as "incised" or "engraved". In the present specification the expression "intagliated article" means a solid article which has at least one figure, mark or notation, or any combination thereof, formed on the surface of the article by a compression punching, incision or engraving procedure, or by any other procedure which produces a like effect.

"optically anisotropic substance" - An anisotropic substance is one which shows differences of property or effect in different directions. As it is used in this specification, the expression "optically anisotropic substance" means any substance which exhibits different refractive indices in different directions and which has a minimum refractive index not greater than 2.00.

Various methods are used in the pharmaceutical industry for putting product names, active ingredient information, company identifying marks, and/or like information, on the surface of unit dosage forms such as tablets. For example, one known method involves

applying printed information or the like on to coated unit dosage forms, for example film coated tablets. Another method involves the use of intagliated unit dosage forms where the information or the like is presented on the surface of the dosage forms in the form of intagliations. In the said method involving printed information or the like, the information or the like can be applied in the form of one or more colours. However, printing is a relatively difficult, slow and costly procedure, and it involves the use of specialised machinery. By contrast, the process of this invention involves the use of coating apparatus (different versions of which are widely used in industry), it is a cheap and rapid process, and the products obtained are superior to those obtained by the said method involving printing. In the said known method involving intagliations, it has not been possible heretofore to produce intagliated unit dosage forms in which the intagliations are in a different colour from the remainder of the dosage form. The present invention remedies that deficiency.

We have found that if a coloured (i.e. non-white) intagliated tablet (which may or may not already bear a film coat) is coated in a side-vented perforated coating drum with a film coat comprising an optically anisotropic substance and a film coating agent, the colour of the non-intagliated part of the tablet is very little changed from the original colour, but the intagliations become coloured in a contrasting manner, and therefore they are highlighted. We believe that the scientific explanation for the result achieved may be as follows, but it is to be understood that we are not certain that this explanation is the correct one, and the scope of this invention is in no way to be limited by this explanation: during the coating process the optically anisotropic substance orientates itself

in the film coat over the non-intagliated part of the tablet so that its refractive index is similar to that of the said film coat, that is, it appears essentially transparent; in the intagliations the optically anisotropic substance orientates itself in the film coat so that its refractive index exceeds that of said film coat, that is, it appears relatively opaque. Thus, the net effect is that the intagliations show up in a distinctive and attractive way against a coloured background, and the intagliated information is much easier to read.

It is known to include an optically anisotropic substance such as calcium carbonate, magnesium carbonate, sucrose or lactose in film coating compositions, but it is not known, nor is it obvious, to apply such film coating compositions to coloured intagliated articles, for example coloured intagliated tablets, in order to highlight the intagliations.

The present invention is capable of wide application, and it is to be understood that it is not solely restricted to the pharmaceutical field. Thus, for example, it can be applied in the veterinary field, for example in the preparation of boluses (i.e. veterinary tablets), or in the confectionery field, for example in the preparation of sugar confectionery (i.e. sweets or candy), and in other fields where it is desirable to have intagliated articles in which the intagliations are highlighted.

It is to be understood that in this specification a coloured article means a non-white article.

According to the invention there is provided
5 a coloured solid article bearing at least one high-lighted intagliation, which comprises a coloured intagliated article bearing at least one film coat comprising at least one optically anisotropic substance having a minimum refractive index not greater than
10 2.00 and at least one film coating agent.

Prior to the application of the film coat which characterises this invention, the coloured intagliated article may be uncoated, for example it may be an uncoated medicinal tablet or bolus.
15 Alternatively, prior to the application of the film coat which characterises this invention, the coloured intagliated article may bear at least one film coat, for example it may be a film coated medicinal tablet or bolus, or a film coated piece of sugar confectionery.
20 The optional film coat, which may be present on the article prior to the application of the film coat which characterises this invention, may comprise any film coating agent or agents known in the art, for example a cellulose ether, for example methyl-
25 cellulose, ethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxypropyl methylcellulose or sodium carboxymethylcellulose, or a mixture thereof, or cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, polyvinyl acetate, polyvinyl
30 acetate phthalate, cellulose acetate, shellac or an

- acrylic resin, or a mixture thereof. The optional film coat may contain one or more adjuvants which are conventional in the film coating art, for example plasticisers, surface active agents and/or waxes.
- 5 The optional film coat is applied in conventional manner using conventional apparatus (see below) and using either an organic solvent-based coating process, for example a process involving a mixture of methylene dichloride and methanol, or an aqueous coating process.
- 10 The colour, which characterises the intagliated article prior to the application of the film coat which characterises this invention, may be present throughout the article, or it may be applied to the surface of the article. Thus, a coloured substance, for
- 15 example a coloured medicinal or veterinary agent in the case of medicinal or veterinary intagliated articles, or a colouring agent, may be present throughout the article, or a colouring agent may be applied as such, or in the form of a coloured film coat, to
- 20 the surface of the article. Any conventional colouring agent which is approved for the general purpose in question, for example pharmaceutical purposes, may be used, for example iron oxide (red, yellow or black), carmine, natural dyes, for example turmeric or beta-
- 25 carotene, water-soluble dyes, for example tartrazine, or aluminium lakes of water-soluble dyes, or any mixture thereof, optionally in admixture with at least one opaque white pigment, for example titanium dioxide.

It is to be understood that the general description hereinafter concerning the optically anisotropic substances, film coating agents and colouring agents which can be used according to this invention is phrased in the singular for ease of reading and comprehension, but it applies also to mixtures of two or more of said optically anisotropic substances, film coating agents and/or colouring agents.

The optically anisotropic substance is used according to this invention in the form of a powder. As suitable optically anisotropic substances there may be mentioned, for example, white optically anisotropic substances, for example known transparent white pigments (also known as "extender" or "inert" white pigments), for example aluminium hydroxide, china clay (kaolin), talc, calcium carbonate or barium carbonate. Other suitable optically anisotropic substances are magnesium carbonate (light or heavy form), cane sugar (sucrose), lactose or tartaric acid. Alternatively, in the case of a medicinal tablet or bolus the medicinal or veterinary agent present therein may also be used as the optically anisotropic substance. That is, the medicinal or veterinary agent may be used in a dual role: as both the active agent in the tablet or bolus and as the optically anisotropic substance.

Suitable film coating agents for use in the film coat(s) which characterise(s) this invention are mentioned above.

As aforesaid, the optically anisotropic substance has a minimum refractive index not greater than 2.00. The choice of this substance depends upon the film coating agent applied therewith (i.e. in the same coating suspension) in that an optically anisotropic substance should be used which has a minimum refractive index which is the same as or similar to the refractive index of the film coating agent. It is an advantage to use an optically anisotropic substance which has a maximum refractive index which is as different as possible from its minimum refractive index, as this affords the best visual results. Details on typical materials which can be used according to the present invention are as follows:-

	<u>Film coating agents</u>	<u>Refractive index</u>
	Methylcellulose	1.50
	Ethylcellulose	1.47
	Hydroxyethylcellulose	1.51
20	Hydroxypropylcellulose	1.56
	Hydroxypropyl methylcellulose	1.49
	Sodium carboxymethylcellulose	1.52
	Cellulose acetate	1.48
	Shellac	1.52
25	Acrylic resin	1.48

	<u>Optically anisotropic substances</u>	<u>Refractive indices</u>	
		<u>Minimum</u>	<u>Maximum</u>
	Aluminium hydroxide	1.50	1.56
	Kaolin	1.56	1.57
30	Talc	1.54	1.59
	Calcium carbonate	1.51	1.65

	<u>Optically anisotropic substances</u>	<u>Refractive indices</u>	
		<u>Minimum</u>	<u>Maximum</u>
	Calcium sulphate	1.57	1.61
	Barium carbonate	1.53	1.68
5	Magnesium carbonate	1.51	1.70
	Cane sugar	1.54	1.57
	α -Lactose	1.52	1.57
	Tartaric acid	1.50	1.61

10 The amount of optically anisotropic substance that
 is applied depends upon the degree of colour contrast
 required, the refractive indices of the substance,
 and its particle size. Thus, for example, in the
 case where the film coating agent is hydroxypropyl
 methylcellulose and intagliated tablets are used as
 15 starting material and themselves carry a film coat which
 is coloured with red or black iron oxide, the amounts
 of optically anisotropic substance which are used
 (expressed as % w/w of tablet weight) vary between 0.1
 and 1.0%. In the case of corresponding tablets which
 20 carry a film coat coloured in more pastel shades, the
 said amounts vary between 0.5 and 5.0%. Approximately
 three times as much heavy magnesium carbonate, compared
 to light magnesium carbonate, is required to achieve the
 same effect.

25 The mixture of optically anisotropic
 substance and film coating agent may optionally contain
 one or more film coating adjuvants which are conventional
 in the film coating art, for example plasticisers, for
 example glycerol, propyleneglycol, polyethyleneglycol,
 30 diethyl phthalate, glyceryl monostearate or castor oil,
 and surface active agents, for example polyoxyethylene
 sorbitan monooleate ['Tween' 80 ('Tween' is a Trade
 Mark)], and waxes, for example beeswax or carnauba wax.

Alternatively or additionally, the said mixture may optionally contain at least one colouring agent, for example one or more of the specific colouring agents mentioned above. By this means it is possible to
5 obtain colour combinations essentially similar to those described below in respect of the situation where there is present, on top of the film coat(s) comprising at least one optically anisotropic substance and at least one film coating agent, at least one
10 additional film coat comprising at least one colouring agent.

According to a further feature of the invention, the articles of the invention may optionally carry, on top of the film coat(s) comprising at least
15 one optically anisotropic substance and at least one film coating agent, at least one additional film coat. The latter (hereinafter "outer") film coat(s) comprise(s) one or more conventional film coating agents and optionally one or more conventional film coating
20 adjuvants, as described hereinbefore, and it is or they are applied in conventional manner. The outer film coat(s) may in addition comprise at least one colouring agent so as to provide at least one coloured outer film coat. Where more than one such coat is
25 present, each such coat may contain the same or different colouring agent(s). The net effect of this embodiment of the invention is that the colours in question [i.e. the colour of the main body of the article and the colour of the intagliations, on the
30 one hand, and the colour(s) of the outer film coat(s), on the other] interact in a subtractive manner [see Encyclopaedia Britannica, Micropaedia, Volume III, 1974, 22]. Numerous colour combinations are thus possible,

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the intagliations normally being seen as a pale version of the colour of the outer coat(s). If the colour of the main body of the article and that of the outer film coat(s) are so-called complementary colours (see above reference), the main body of the article is seen as black and the intagliations are seen as a pastel colour [i.e. a pale version of the colour of the outer coat(s)].

According to one embodiment of this invention, therefore, there is provided a coloured intagliated article consisting of:

- (a) a first coloured intagliated article, which carries
- (b) at least one film coat which comprises at least one optically anisotropic substance, at least one film coating agent, and optionally at least one colouring agent of the same or a different colour from that of the said first coloured intagliated article, and, on the outside of this coat or these coats
- (c) at least one film coat which comprises at least one film coating agent and at least one colouring agent of the same or a different colour from that of said first coloured intagliated article.

Another embodiment of this invention comprises a coloured intagliated solid medicinal or veterinary unit dosage form, for example a tablet or bolus, comprising at least one medicinal or veterinary agent, characterised by at least one film coat comprising at least one optically anisotropic substance, at least one

film coating agent, and optionally at least one film coating adjuvant which is known in the film coating art.

5 As indicated above, the present invention is widely applicable, and therefore the precise nature of the said medicinal or veterinary agent is not critical.

10 Another embodiment of this invention comprises a coloured intagliated piece of sugar confectionery falling under the general term sweets or candy, characterised by at least one film coat comprising at least one optically anisotropic substance, at least one film coating agent, and optionally at least one film coating adjuvant which is known in
15 the film coating art.

It is to be understood that:

- (a) the said film coat(s) comprising at least one optically anisotropic substance and at least one film coating agent, and
- 20 (b) any film coat(s) applied on top of the said film coat(s) (a), appear(s) transparent or translucent [except that, as indicated above, the film coat(s) (a) appear(s) opaque in the intagliations]. That is to say, as
25 skilled persons will appreciate, in order to obtain the desired results according to the present invention it is necessary for the viewer to be able to see through the film coat(s) in question to a reasonable extent.

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According to a further feature of the invention there is provided a process for the manufacture of a coloured solid article bearing at least one highlighted intagliation, which comprises applying
5 to a coloured intagliated article, which itself may be uncoated or coated, a film coating suspension comprising at least one optically anisotropic substance having a minimum refractive index not greater than 2.00 and at least one film coating agent, which
10 process is carried out in a conventional film coating apparatus such that a rubbing action takes place between the articles being coated.

The coloured intagliated article used as starting material may be produced in any known
15 manner using known materials. For example, solid medicinal or veterinary unit dosage forms, for example tablets or boluses, may be produced in conventional manner using conventional excipients and the appropriate active agent(s).

20 The optically anisotropic substance and film coating agent, and any film coating adjuvant and/or colouring agent applied therewith, are applied in the form of a coating suspension which may be an organic solvent-based suspension, for example where
25 the solvent is a mixture of methylene dichloride and methanol, or an aqueous suspension. When all of the ingredients are water-soluble, they should be applied in an organic solvent-based suspension. The film coating procedure is carried out using a conventional
30 film coating apparatus or machine, for example a

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coating pan, or a coating drum, for example a side-vented perforated coating drum, or a so-called Wurster coating apparatus (a fluidized bed coating apparatus). It is to be understood that a rubbing
5 action between the intagliated articles being coated, that is the rubbing action that usually takes place between articles being coated in any conventional film coating apparatus or machine, is an essential feature of the process of this invention.

10 The invention is illustrated but not limited by the following Examples (it is to be understood that the placebo tablets contained no medicinal agent, whereas the medicinal tablets contained a medicinal agent):-

15 Example 1

A batch of 50,000 200mg. intagliated white tablets (a mixture of placebo tablets and medicinal tablets), coated with a film coat coloured with red iron oxide, was heated to 60°C. in a side-vented
20 perforated coating drum (24 inch Accela-Cota machine; obtainable from Manesty Machines Ltd., Speke, Liverpool 24, England). 4 litres of a 5% w/v aqueous solution of hydroxypropyl methylcellulose ['Pharmacoat' (Trade Mark) 606, Shin-Etsu Chemical
25 Company Limited, Tokyo, Japan], containing 1% w/v glycerol, and containing calcium carbonate (30g.) suspended therein, were applied continuously at 50ml./min. by means of a low pressure air-spray unit. The drum speed was kept at 16rpm and the temperature of the
30 inlet drying air at 60°C. When the suspension had all been applied, the drum was stopped and the tablets removed. There were thus obtained red-brown film coated tablets with intagliations highlighted in white.

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Example 2

The process described in Example 1 was repeated except that the tablets used as starting material had previously been coated with a film coat coloured with a mixture of carmine and titanium dioxide, and the coating suspension applied contained light magnesium carbonate (60g.) in place of the calcium carbonate, and 1% w/v polyethyleneglycol in place of the glycerol. There were thus obtained pink film coated tablets with intagliations highlighted in white.

Example 3

A batch of 50,000 200mg. intagliated white tablets (a mixture of placebo tablets and medicinal tablets), coated with a film coat coloured with red iron oxide, was heated to 60°C. in a side-vented perforated coating drum (24 inch Accela-Cota machine). 10 litres of a 2% w/v solution of hydroxypropyl methylcellulose ('Pharmacoat' 606) in methylene dichloride: methanol (70:30 v/v) containing 0.4% w/v glycerol, and containing aluminium hydroxide (90g.) suspended therein, were applied continuously at 250ml./min. by means of a high pressure airless spray unit. The drum speed was kept at 20 rpm and the temperature of the inlet drying air at 60°C. When the suspension had all been applied, the drum was stopped and the tablets removed. There were thus obtained red-brown film coated tablets with intagliations highlighted in white.

Example 4

A batch of 50,000 200mg. intagliated carmine coloured tablets (a mixture of coated placebo tablets

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and uncoated medicinal tablets) was heated to 60°C. in a side-vented perforated coating drum (24 inch Accela-Cota machine). 1 litre of a 5% w/v aqueous solution of hydroxypropyl methylcellulose ('Pharmacoat' 5 606) containing 1% w/v glycerol, and containing light magnesium carbonate (30g.) dispersed therein, was applied continuously at 50ml./min. by means of a low pressure air-spray unit. The drum speed was kept at 16 rpm and the temperature of the inlet drying 10 air was kept at 60°C. When the suspension had all been applied, the drum was stopped and the tablets removed. There were thus obtained pink film coated tablets with intagliations highlighted in white.

Example 5

15 To a batch of 50,000 200mg. white placebo tablets were added approximately 100 coloured, film coated, intagliated tablets (a mixture of placebo tablets and medicinal tablets), some of which were coloured grey with intagliations highlighted in 20 white and others of which were coloured carmine with intagliations highlighted in white (these tablets were obtained as described below). The resulting mixed batch of tablets was heated to 60°C. in a side-vented perforated coating drum (24 inch Accela- 25 Cota machine). 1 litre of a 3.3% w/v aqueous solution of hydroxypropyl methylcellulose ('Pharmacoat' 606) containing tartrazine water-soluble yellow dye (1g.) and 0.66% w/v glycerol (plasticiser) was applied continuously at 50ml./min. by means of a low pressure 30 air-spray unit. The drum speed was kept at 14 rpm and the temperature of the inlet drying air at 60°C.

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When the solution had all been applied, the drum was stopped and the tablets removed. There was thus obtained inter alia:

- 5 (i) green film coated intagliated tablets with the intagliations highlighted in pale yellow (from the original grey tablets), and
- (ii) orange-brown film coated intagliated tablets with the intagliations highlighted in pale yellow (from the original carmine tablets).

10 The said grey and carmine film coated, intagliated tablets used in the above process were prepared from 80-650mg. intagliated white tablets (a mixture of placebo tablets and medicinal tablets) which were first coated with a film coat which was
15 coloured with either a mixture of black iron oxide and titanium dioxide or a mixture of carmine and titanium dioxide, respectively. The resulting coloured film coated tablets were then coated with a suspension comprising hydroxypropyl methylcellulose
20 and light magnesium carbonate as described in Example 4. There were thus obtained the said highlighted grey tablets and carmine tablets, respectively.

Example 6

25 To a batch of 50,000 200mg. white placebo tablets were added approximately 100 differently coloured, film-coated, intagliated tablets (a mixture of placebo tablets and medicinal tablets) in which the intagliations were highlighted in white (the said coloured tablets included some red-brown
30 intagliated tablets which were obtained as described

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below). The resulting mixed batch of tablets was heated to 60°C. in a side-vented perforated coating drum (24 inch Accela-Cota machine). 1 litre of a 3.3% w/v aqueous solution of hydroxypropyl methyl-cellulose ('Pharmacoat' 606) containing Brilliant Blue FCF water-soluble dye (Food, Drugs and Cosmetics Blue No. 1; 0.25g.) and 0.66% w/v glycerol (plasticiser) was applied continuously at 50ml./min. by means of a low pressure air-spray unit. The drum speed was kept at 14 rpm and the temperature of the inlet drying air at 60°C. When the solution had all been applied, the drum was stopped and the tablets removed. There were thus obtained inter alia black film coated intagliated tablets with the intagliations highlighted in pale blue (obtained from the original red-brown intagliated tablets).

The said red-brown tablets were prepared from approx. 200-400mg. intagliated white tablets which were first coated with a film coat which was coloured with red iron oxide. The resulting film coated tablets were then coated with a suspension comprising hydroxypropyl methylcellulose and light magnesium carbonate as described in Example 4. There were thus obtained the said red-brown intagliated tablets with the intagliations highlighted in white.

Example 7

To a batch of 50,000 200mg. white placebo tablets were added approximately 100 415mg. red-brown film coated intagliated tablets (the latter tablets were a mixture of placebo tablets and medicinal

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tablets, and they were coated with a film coat which was coloured with red iron oxide). 1 litre of a 3.3% w/v aqueous solution of hydroxypropylmethyl-cellulose ('Pharmacoat' 606) containing Brilliant Blue FCF water-soluble dye (0.25g.) and 0.66% w/v glycerol, and having light magnesium carbonate (30g.) dispersed therein, was applied to the mixed batch of tablets in a side-vented perforated coating drum (24 inch Accela-Cota machine). The suspension was applied continuously at 50ml./min. by means of a low pressure air-spray unit. The drum speed was kept at 16 rpm and the temperature of the inlet drying air at 60°C. When the suspension had all been applied, the drum was stopped and the tablets removed. There were thus obtained inter alia black film coated tablets with the intagliations highlighted in pale blue (obtained from the original red-brown film coated intagliated tablets).

WHAT WE CLAIM IS:-

1. A coloured solid article bearing at least one highlighted intagliation, which comprises a coloured intagliated article bearing at least one
5 film coat comprising at least one optically anisotropic substance having a minimum refractive index not greater than 2.00 and at least one film coating agent.
2. An article as claimed in claim 1 which
10 is a pharmaceutical tablet or a bolus.
3. An article as claimed in claim 1 which is a piece of sugar confectionery.
4. An article as claimed in any one of claims 1 to 3 in which, prior to the application of the
15 film coat or coats comprising at least one optically anisotropic substance and at least one film coating agent, the intagliated article bears at least one film coat comprising at least one colouring agent.
5. An article as claimed in any one of claims
20 1 to 4 in which the colour is due to the presence of at least one colouring agent selected from red, yellow and black iron oxide, carmine, natural dyes, water-soluble dyes, and aluminium lakes of water-soluble dyes, and any mixture thereof.
- 25 6. An article as claimed in claim 5 in which the colouring agent or agents is or are in admixture with at least one opaque white pigment.

7. An article as claimed in claim 6 in which the opaque white pigment is titanium dioxide.
8. An article as claimed in any one of claims 1 to 7 in which the optically anisotropic substance is white.
9. An article as claimed in claim 8 in which the optically anisotropic substance is a known transparent white pigment or magnesium carbonate, sucrose, lactose or tartaric acid.
10. An article as claimed in claim 1 or 2 containing a medicinal or veterinary agent, in which the medicinal or veterinary agent is also used as the optically anisotropic substance.
11. An article as claimed in any one of claims 1 to 10 in which the film coating agent is a cellulose ether or cellulose acetate phthalate, hydroxypropyl methylcellulose phthalate, polyvinyl acetate, polyvinyl acetate phthalate, cellulose acetate, shellac or an acrylic resin, or any mixture thereof.
12. An article as claimed in any one of claims 1 to 11 in which the film coat contains at least one film coating adjuvant selected from plasticisers, surface active agents and waxes.
13. An article as claimed in any one of claims 1 to 12 in which the optically anisotropic substance has a minimum refractive index which is the same as or similar to the refractive index of the film coating agent, and it has a maximum refractive index which is as different as possible from its minimum refractive index.

14. An article as claimed in any one of claims 1 to 13 in which the film coat or coats, comprising at least one optically anisotropic substance and at least one film coating agent, contains or contain
5 at least one colouring agent.

15. An article as claimed in any one of claims 1 to 14 which carries, on top of the film coat or coats comprising at least one optically anisotropic substance and at least one film coating agent, at
10 least one outer film coat comprising at least one film coating agent.

16. An article as claimed in claim 15 in which the said outer film coat or coats comprises or comprise at least one colouring agent.

15 17. A coloured solid article bearing at least one highlighted intagliation, which comprises a coloured intagliated article bearing at least one film coat comprising at least one film coating agent and at least one optically anisotropic sub-
20 stance selected from known transparent white pigments and magnesium carbonate, sucrose, lactose and tartaric acid.

18. An article as claimed in claim 17 in which the transparent white pigment is aluminium
25 hydroxide, kaolin, talc, calcium carbonate or barium carbonate.

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19. An article as claimed in claim 17 or 18 which is a pharmaceutical tablet or a bolus.

20. An article as claimed in claim 17 or 18 which is a piece of sugar confectionery.

5 21. A process for the manufacture of an article as claimed in claim 1, which comprises applying to a coloured intagliated article a film coating suspension comprising at least one optically anisotropic substance having a minimum refractive index not
10 greater than 2.00 and at least one film coating agent, which process is carried out in a conventional film coating apparatus such that a rubbing action takes place between the articles being coated.

22. A process as claimed in claim 21 which
15 is carried out in a coating drum.

R. Allerton

ROY ALLERTON

AUTHORISED REPRESENTATIVE
General Authorisation No. 97

PH. 31725/EP

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WHAT WE CLAIM IS:-

1. A process for the manufacture of a coloured solid article bearing at least one highlighted intagliation, which comprises applying to a coloured
5 intagliated article a film coating suspension comprising at least one optically anisotropic substance having a minimum refractive index not greater than 2.00 and at least one film coating agent, which process is carried out in a conventional film coating
10 apparatus such that a rubbing action takes place between the articles being coated.
2. A process as claimed in claim 1 in which the article is a pharmaceutical tablet or a bolus.
3. A process as claimed in claim 1 or 2 which
15 is carried out in a coating pan, a coating drum, or a fluidized bed coating apparatus.
4. A process as claimed in any one of claims 1 to 3 in which, prior to the application of the said film coating suspension, the intagliated article
20 bears at least one film coat comprising at least one colouring agent.
5. A process as claimed in claim 4 in which the colouring agent is in admixture with at least one opaque white pigment.
- 25 6. A process as claimed in any one of claims 1 to 5 in which the optically anisotropic substance is white.

7. A process as claimed in claim 6 in which the optically anisotropic substance is a known transparent white pigment or magnesium carbonate, sucrose, lactose or tartaric acid.
- 5 8. A process as claimed in claim 1 or 2 in which the intagliated article contains a medicinal or veterinary agent, and in which the said medicinal or veterinary agent is used as the optically anisotropic substance.
- 10 9. A process as claimed in any one of claims 1 to 8 in which the optically anisotropic substance has a minimum refractive index which is the same as or similar to the refractive index of the film coating agent, and it has a maximum refractive index
15 which is as different as possible from its minimum refractive index.
10. A process as claimed in any one of claims 1 to 9 in which the film coat or coats, comprising at least one optically anisotropic substance and at
20 least one film coating agent, contains or contain at least one colouring agent.
11. A process as claimed in any one of claims 1 to 10 in which there is applied, on top of the film coat or coats comprising at least one optically
25 anisotropic substance and at least one film coating agent, at least one outer film coat comprising at least one film coating agent.

12. A process as claimed in claim 11 in which the outer film coat or coats comprises or comprise at least one colouring agent.

13. A process for the manufacture of a coloured solid article bearing at least one highlighted intagliation, which comprises applying to a coloured intagliated article a film coating suspension comprising at least one film coating agent and at least one optically anisotropic substance selected from known transparent white pigments and magnesium carbonate, sucrose, lactose and tartaric acid, which process is carried out in a conventional film coating apparatus.

14. A coloured non-pharmaceutical solid article bearing at least one highlighted intagliation, which comprises a coloured non-pharmaceutical intagliated article bearing at least one film coat comprising at least one optically anisotropic substance having a minimum refractive index not greater than 2.00 and at least one film coating agent.

15. An article as claimed in claim 14 which is a piece of sugar confectionery.

16. An article as claimed in claim 14 or 15 in which the optically anisotropic substance has a minimum refractive index which is the same as or similar to the refractive index of the film coating agent, and it has a maximum refractive index which is as different as possible from its minimum refractive index.

17. An article as claimed in any one of claims
14 to 16 in which the film coat or coats, comprising
at least one optically anisotropic substance and
at least one film coating agent, contains or contain
5 at least one colouring agent.

18. An article as claimed in any one of claims
14 to 17 which carries, on top of the film coat or
coats comprising at least one optically anisotropic
substance and at least one film coating agent, at
10 least one outer film coat comprising at least one
film coating agent.

19. An article as claimed in claim 18 in which
the outer film coat or coats comprises or comprise
at least one colouring agent.



DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl. 7)
A	<p><u>US - A - 3 125 490</u> (HERSHBERG)</p> <p>* entire document *</p> <p>---</p>		<p>A 61 K 9/44</p> <p>B 44 F 1/08</p> <p>A 23 G 3/00</p> <p>3/28</p>
A	<p>CHEMICAL ABSTRACTS, vol. 89, no. 22, November 1978</p> <p>abstract no. 186090v, page 377</p> <p>COLUMBUS, OHIO (US)</p> <p>& JP - B - 78 31 1211 (DAIICHI SEIYAKU) 1st September 1978</p> <p>---</p>		
A	<p>HAGERS HANDBUCH DER PHARMAZEUTISCHEN PRAXIS, 4th edition, vol. 7, part A, Springer Verlag, 1971</p> <p>BERLIN (DE)</p> <p>pages 693-762</p> <p>* page 693, lines 10-19; page 694, figure 390; pages 761-762, table*</p> <p>---</p>		<p>TECHNICAL FIELDS SEARCHED (Int. Cl. 7)</p> <p>A 61 K 9/00</p> <p>B 44 F 1/00</p> <p>3/00</p> <p>A 61 J 3/00</p>
A	<p><u>US - A - 3 015 610</u> (SANDERS)</p> <p>* entire document *</p> <p>-----</p>		
The present search report has been drawn up for all claims			
Place of search The Hague		Date of completion of the search 17-06-1982	Examiner BENZ
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone</p> <p>Y : particularly relevant if combined with another document of the same category</p> <p>A : technological background</p> <p>O : non-written disclosure</p> <p>P : intermediate document</p> <p>T : theory or principle underlying the invention</p> <p>E : earlier patent document, but published on, or after the filing date</p> <p>D : document cited in the application</p> <p>L : document cited for other reasons</p> <p>& : member of the same patent family, corresponding document</p>			